PATENT Docket No. 229752000800

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September 10, 2001.

SEP 1 4 2001

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TECH CENTER 1600/2900

In the application of:

Gail Peturna RISBRIDGER et al.

Serial No.:

09/402,614

National Phase Entry Date: October 25, 1999

35 U.S.C. 371 Date: March 1, 2000

For:

INHIBIN MODULATION OF CELL

**GROWTH** 

Examiner: Gary B. Nickol, Ph.D.

Group Art Unit: 1642

## RESPONSE TO RESTRICTION/ELECTION OF SPECIES REQUIREMENT

Commissioner for Patents Washington, D.C. 20231

Sir:

In response to the Action mailed March 9, 2001, Applicants elect Group 10, claims 58 and 60-63, with traverse. With respect to the election of species, Applicants provisionally elect the species in relation to the  $\alpha$ C isoform of  $\alpha$  inhibin. Applicants reserve the right to file divisional applications directed to the remaining groups identified by the Examiner.

## **TRAVERSAL**

Applicants request withdrawal of the Examiner's Restriction Requirement in terms of each of Groups 1 through 17. Alternatively, Applicants request withdrawal of the Restriction Requirement as between Groups 10-17.

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Applicants traverse of the Examiner's Restriction Requirement on the ground that Alvarado et al. does not disclose the invention in issue. Applicants submit that the technical feature which links all these claims and defines a contribution over the prior art is the determination that the modulation of inhibin levels can be related to the development of prostate cancer. Applicants note that all of the claims in each of Groups 10-17 specifically relate to a method of diagnosing prostate cancer or predisposition thereto based on changes in the level of expression of inhibin, at either the protein or genomic level, and that almost all of the claims of Groups 1-9 are specific to this feature.

By contrast, *Alvarado*, *et al.* teaches that up-regulation of human chorionic gonadotropin (hCG) leads to lobula development in the mammary gland. *Alvarado*, *et al.* then determine that upregulation of hCG expression results in the induction of expression of inhibin and theorize thereby that inhibin is thereby a regulator of mammary cell growth and differentiation.

Applicants submit that protein hormones such as inhibin are pleotropic molecules and that, therefore, the role of inhibin in regulating mammary cell growth (which role is merely speculated upon by the authors and not proven), cannot not anticipate or render obvious the role of inhibin, if any, in the induction of uncontrolled prostate cell proliferation.

Accordingly, reconsideration and withdrawal of the Restriction Requirement is considered proper, and such action is respectfully requested. If the Examiner is not persuaded that Groups 1-17 all define a common technical feature that defines a contribution over the prior art, Applicants respectfully request withdrawal of the Restriction Requirement as between Groups 10-17, which are all specifically directed to subject matter that is not contemplated by *Alvarado, et al.* 

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to

**Deposit Account No. 03-1952**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

September 10, 2001 Dated:

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